

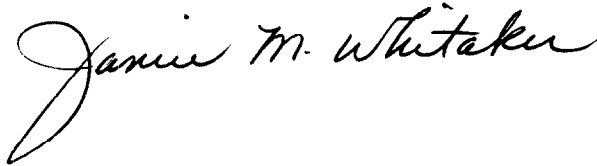
GlaxoSmithKline

[illegible]

C6

In reading this answer (A7), GSK is concerned that this section of the regulation may be interpreted as **all product shipped after April 26, 2006, must comply with the regulation**. If interpreted in this way, the challenge to enforce compliance with the rule will be difficult for both the industry and FDA as it could necessitate relabeling or repackaging goods which have already been packaged but not yet distributed, increasing the potential for disruption of product supply. GSK proposes that the benefits of this interpretation do not outweigh the burden of conducting the repackaging and relabeling operations. Additionally, GSK understands that the FDA did not intend to create such a burden when they developed the implementation date of 2 years from the effective date of the rule (vs. the 3 years which was originally proposed). Therefore, GSK requests that the agency publish an official clarification of the terms of compliance, stating that all products **packaged** on or after April 26, 2006 must contain bar codes.

Sincerely,

A handwritten signature in black ink, reading "Jamie M. Whitaker". The signature is written in a cursive style with a large, stylized initial "J".